

PATENT
Docket: P-11209.05

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant(s): | Walter L. Carpenter, et al |) | Art Unit: 3761 |
| | |) | |
| Serial No.: | 10/743,357 |) | Examiner: Leslie R. Deak |
| | |) | |
| Filed: | 12-22-2003 |) | |
| For: | EXTRACORPOREAL BLOOD CIRCUIT PRIMING SYSTEM AND METHOD | | |

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application.

Consideration of each of the documents listed on the attached Form 1449 is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the Form 1449, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

The filing of this supplemental information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

This information disclosure statement includes some documents from the pending *Cardiovention v. Medtronic* lawsuit in Federal Court in Minnesota. Cardiovention has said the following in court papers:

Cardiovention first presented the CORx disposable IOS without a confidentiality agreement at a trade show on January 24, 2002, accompanied by a short animated video. Later,

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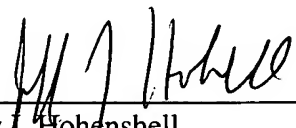
similar information regarding the CORx disposable was placed on CardioVention's website. CardioVention first sold the CORx disposable IOS internationally to a German distributor in November 2001. However, the CORx disposable IOS was not offered or sale to the public in Europe until March 2002 and first sold in the United States on April 17, 2002, after it received FDA clearance.

Enclosed are machine translations (uncertified) of Italian patent application Nos. MO2005A000243 and MO2005A000244.

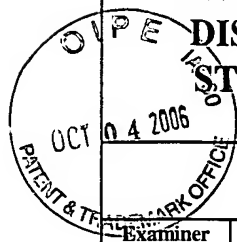
Please charge the fee of \$180.00 pursuant to 37 C.F.R. Section 1.17(p) for the submission of this supplemental information disclosure statement to Deposit Account No. 13-2546.

Respectfully submitted,

Walter L. Carpenter, et al
By their Representatives,

By: 

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Customer No.: 27581



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| | Filing Date: 12-22-2003 | Group: 3761 |

U.S. PATENT DOCUMENTS

| Examiner Initial | Document Number | Date | Name | Class | SubClass | Filing Date If Appropriate |
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FOREIGN PATENT DOCUMENTS

| | Document Number | Date | Country | Class | SubClass | Translation | |
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| | | | | | | Yes | No |
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| | 2005/067998 | 07-28-2005 | WO | | | | |
| | MO2005A000244 | | IT | | | (uncertified machine) | |
| | MO2005A000243 | | IT | | | (uncertified machine) | |

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

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|-----------------|--|
| | Declaration of Jorge Ojito in the matter of United States District Court, District of Minnesota, Civil File No. 04-CV-02669, CardioVention, Inc. v. Medtronic, Inc., executed November 22, 2005. |
| EXAMINER | Date Considered |

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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| OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.) | | | |
| | | Curriculum Vitae of Jorge Ojito, Exhibit 1 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
| | | Drawing of the Venous Pull Circuit dated July 1997, Exhibit 2 to the Declaration of Jorge Ojito executed November 22, 2005 (1 page). | |
| | | Drawing from Katsura U.S. Patent No. 4,919,802, issued on April 24, 1990, Exhibit 3 to the Declaration of Jorge Ojito executed November 22, 2005 (2 pages). | |
| | | Advertising brochure from COBE Cardiovascular for the Century Perfusion System circa 1997, Exhibit 4 to the Declaration of Jorge Ojito executed November 22, 2005 (4 pages). | |
| | | Two pictures of an ultrasonic air sensor allegedly used on the Venous Pull Circuit in 1997 and 1998, Exhibit 5 to the Declaration of Jorge Ojito executed November 22, 2005 (2 pages). | |
| | | Picture of the Venous Pull Circuit, Exhibit 6 to the Declaration of Jorge Ojito executed November 22, 2005 (1 page). | |
| | | Ojito, et al., "Assisted Venous Drainage Cardiopulmonary Bypass in Congenital Heart Surgery," Ann. Thorac. Surg., 2001;71:1267-72, Exhibit 7 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
| | | Custom Tubing Pack Specification, Exhibit 8 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
| | | Medtronic Cardiopulmonary personnel business cards, Exhibit 9 to the Declaration of Jorge Ojito executed November 22, 2005 (1 page). | |
| | | Circulacion Extracorporea presentation brochure, Exhibit 10 to the Declaration of Jorge Ojito executed November 22, 2005 (4 pages). | |
| | | Certificate of participation of Jorge Ojito, Exhibit 11 to the Declaration of Jorge Ojito executed November 22, 2005 (2 pages). | |
| | | AmSECT Region XI Annual Fall Meeting agenda, Exhibit 12 to the Declaration of Jorge Ojito executed November 22, 2005 (2 pages). | |
| | | PowerPoint presentation regarding Assisted Venous Drainage Cardiopulmonary Bypass: Safety and Efficacy in Congenital Heart Surgery, Jorge W. Ojito, Exhibit 13 to the Declaration of Jorge Ojito executed November 22, 2005 (48 pages). | |
| | | United States Patent 6,302,860, Exhibit 14 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
| | | United States Patent 6,524,267, Exhibit 15 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
| | | Gremel I patent comparison chart, Exhibit 16 to the Declaration of Jorge Ojito executed November 22, 2005 (4 pages). | |
| | | Gremel II patent comparison chart, Exhibit 17 to the Declaration of Jorge Ojito executed November 22, 2005 (5 pages). | |
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| OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.) | | | |
| | | | Mueller, et al., "A new concept of integrated cardiopulmonary bypass circuit," European Journal of Cardio-thoracic Surgery 21 (2002) 840-846. |
| | | | Morita, et al., "Closed Circuit Cardiopulmonary Bypass with Centrifugal Pump for Open-Heart Surgery: New Trial for Air Removal," Artificial Organs 2000; 24(6):442-445. |
| | | | Jegger, et al., "Introduction & Description of CardioVention's CORx System. A replacement technology for traditional cardiopulmonary bypass," Dept of Cardiovascular Surgery, Centre Hospitalier Universitaire Vaudois (CHUV), Switzerland (9 pages). |
| | | | Instructions for Use CORx System, CardioVention, Inc., Santa Clara, CA, 2001 (21 pages). |
| | | | Complaint in CardioVention, Inc. v. Medtronic, Inc., U.S. District Court, District of Minnesota, Civil File No. 04-CV-02669 (16 pages). |
| | | | Declaration of Ben F. Brian, Ph.D., in CardioVention, Inc. v. Medtronic, Inc., U.S. District Court, District of Minnesota, Civil File No. 04-CV-02669 (13 pages). |
| | | | Plaintiff's Answers and Objections to Defendant's First Set of Interrogatories to Plaintiff in CardioVention, Inc. v. Medtronic, Inc., U.S. District Court, District of Minnesota, Civil File No. 04-CV-02669 (11 pages). |
| | | | Memorandum of Law & Order in CardioVention, Inc. v. Medtronic, Inc., U.S. District Court, District of Minnesota, Civil File No. 04-CV-02669 (18 pages). |
| | | | CardioVention CORx System 510(k) Summary dated June 16, 2001 (8 pages). |
| | | | Matayoshi, et al., "Development of a Completely Closed Circuit Using an Air Filter in a Drainage Circuit for Minimally Invasive Cardiac Surgery," Artificial Organs, 24(6):454-458, 2000. |
| | | | McCusker, et al., "High-flow femoro-femoral bypass utilizing small cannulae and a centrifugal pump on the venous side," Perfusion 1992; 7:295-300. |
| | | | Hatteland, "Doppler Ultrasound Application in Cardiology and Cardiac Surgery," from the Thoracic Surgical Clinic, Karolinska Institutet, Stockholm, Sweden, 1985 (6 pages). |
| | | | Memorandum in Support of Plaintiff's Motion to Compel Production of Documents in CardioVention, Inc. v. Medtronic, Inc., U.S. District Court, District of Minnesota, Civil File No. 04-CV-02669 (22 pages). |
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